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SUBJECT: UPDATE ON PHARMACEUTICAL IPR ISSUES IN MEXICO

Summary

¶1. (SBU) Embassy officials met with the head of Mexico's Federal Commission of Health Risk Protection (COFEPRIS - rough equivalent of the U.S. Food and Drug Administration) to discuss issues of concern to U.S. drugmakers, including data protection, patent linkage, and Mexico's proposed elimination of the requirement that would-be pharmaceutical vendors must have production facilities in Mexico. The following day emboffs met with representatives of the U.S. pharmaceutical industry to compare notes and strategize on how best to push Mexico on data protection, the IPR issue of greatest importance to the industry. End summary.

COFEPRIS Commissioner

¶2. (SBU) Juan Antonio Garcia Villa, COFEPRIS Commissioner, and three of his top staff met with Embassy FCS, EST, and ECONoffs on July 10 to discuss issues of concern. Regarding Mexico's lack of regulations to implement its NAFTA commitment (Article 1711) to provide at least five years of protection against disclosure of data that companies must submit to health authorities in order to receive health approval, Garcia Villa agreed that there was a gap in Mexican law. He then pointed out that international agreements themselves have the force of law in Mexico, thus suggesting that the NAFTA text itself was sufficient basis for data protection. Emboffs replied that companies would be understandably reluctant to pursue legal claims in Mexico with nothing other than a copy of the NAFTA in hand. Garcia Villa pointed out that, despite the lack of legal or regulatory guidance, COFEPRIS was very careful in handling data from companies seeking health approval. His staff complained that this task is made more difficult when companies label everything included in their application packets as confidential, putting a strain on the ability of COFEPRIS to secure such large quantities documents. They also pointed out that, in many cases, companies insist on protecting data that is already accessible in the public domain.

¶3. (SBU) Emboffs raised the issue of the pharmaceutical patent linkage instituted via presidential decree in 2003, praising COFEPRIS for its 2007 record of not issuing a single health approval for a drug protected by a valid Mexican patent, but inquiring about the legal status of the dozen health approvals issued the year before for patent-protected drugs. Garcia Villa replied that the twelve cases in question involved patents that had already expired and for which the original patent holders were seeking extensions. The view of COFEPRIS was that, with the patents expired, there was no reason for COFEPRIS to deny health approval to generic drug-maker applicants. That said, the original patent-holders had initiated legal proceedings by arguing that approvals should not have been issued while their patent

extension applications were still pending. Garcia Villa said these cases will be resolved by the courts and thus are no longer in the hands of COFEPRIS or any other executive branch agency.

¶4. (SBU) Garcia Villa commented that the GOM's decision to eliminate its plant requirement for pharmaceutical vendors was at least in part motivated by complaints made by El Salvador that this rule violated national treatment under the terms of the two countries' free trade agreement. As a result of this change, COFEPRIS will soon have to meet the challenge of certifying the safety and efficacy of pharmaceutical products imported from other countries. To meet the new demand, Garcia Villa said COFEPRIS planned to increase its personnel, would seek to contract certified private companies to perform health checks on less sensitive products, and would consider reciprocal agreements to recognize the health approvals of select trading partner governments.

Industry Representatives

¶5. (U) On July 11, Emboffs met with representatives of the Pharmaceutical Research and Manufacturers of America (PhRMA) to discuss the same set of issues from the U.S. industry perspective. The PhRMA reps, who had met separately with COFEPRIS earlier in the same week, said they were not opposed to the elimination of the plant requirement, though specific member companies might be affected. They also remarked on COFEPRIS' recent good record in respecting the patent linkage when considering health approval applications for drugs.

¶6. (SBU) They asserted that the industry's main IPR concern

in Mexico is getting the GOM to formulate clear rules on data protection. They were convinced that legislating such rules would be hard if not impossible to achieve in the near term future given the current state of politics in the Mexican congress. Thus, even though legislation was the desired long-term end point, for now they planned to concentrate on seeking executive branch regulations on data protection. Such regulations are vulnerable to being discarded by subsequent administrations, unlike rules enshrined in law, but they pointed out that the pharmaceutical patent linkage decree issued by the previous administration of President Fox was proving to be effective, at least at present. The industry has submitted a proposal to the Mexican Secretariat of Economy (the bureaucratic parent of the Mexican Institute of Industrial Property, or IMPI, the rough equivalent of the U.S. Patent and Trademark Office) on establishing clear and NAFTA-consistent data protection rules and believes that Economy Secretary Sojo might be willing to act on this proposal. The PhRMA reps requested that the Embassy urge him to do so. They noted one tactical concern -- apparently some European embassies are planning to make a push for a legislative amendment, an initiative that PhRMA believes would expose the whole initiative to unwelcome political manipulation. At the urging of Emboffs, the PhRMA reps agreed to discuss the relative merits of the legislative versus the regulatory approach with their European industry counterparts and lobby their respective embassies to go for the more sure bet of a relatively low-key regulatory solution to this problem. Depending on the response, this Embassy stands ready to coordinate with other embassies in lobbying for clear and NAFTA-consistent data protection rules.

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